

## REMARKS

### Rejection under 35 U.S.C. § 102(b)

Claims 1-6 and 8-12 are rejected under 35 U.S.C. § 102 (b) as being anticipated by Dalemans, et al. (WO 99/30733).

Claims 1 and 10 have been amended as discussed during the interview of Feb. 4, 2010, summarized herein. These amendments correspond to proposed claim 1-1 which was faxed to the Examiner prior to the interview for her consideration and which is also reproduced in the interview summary.

The present claims are amended to more clearly describe that a complex is formed between the “protein antigen immunogenic component comprising at least one protein antigen” and the “mineral-based, negatively charged adjuvant” in component (a) of the claimed immunogenic composition which is combined with (b) which is “a polynucleotide immunogenic component comprising at least one polynucleotide encoding at least one antigen”. As previously argued, Dalemans, et al. do not teach this “preincubating or subsequently mixing” of the protein antigen and the mineral-based, negatively charged adjuvant.

During the interview, the Examiner pointed to the statement in Dalemans, et al. at page 4, lines 13-14 that “Optionally, the polypeptide may be adjuvanted as well”, but noted that Dalemans, et al. here do not teach specifically a “mineral-based, negatively charged adjuvant” as per Applicants’ claims, so that she would not consider this statement as anticipating for proposed claim 1-1, presented prior to the interview and now presented formally with this supplemental amendment.

By forming the mineral-adsorbed adjuvanted protein composition of (a) of claims 1 and 10, a Th2 immunological response characterized by a strong predominance of subtype IgG1 antibodies is achieved as discussed in the present application (see paragraph 0039 of published U.S. application corresponding to pages 7-8, bridging paragraph of the present specification). The immunogenic compositions of the claimed invention provide a sufficient Th1 and a sufficient Th2 response *within the same vaccine preparation* which was unexpected in view of the art including Dalemans. By pre-incubating the negatively charged, mineral-based adjuvant with the protein antigen vaccine component prior to formulating with the polynucleotide vaccine component, both a Th1 and a Th2 response is obtained after administration of the vaccine.

Furthermore, Applicants assert that the present claims are patentable over Dalemans, et al. in view of the unexpected difference in immune response obtained using a negatively charged mineral-based adjuvant compared to a positively charged mineral based adjuvant as discussed in the January 21, 2010 response. This effect was unexpected in view of Dalemans, et al. who teach no difference between positive and negatively charged mineral-based adjuvants. Indeed, the teaching of Dalemans, et al. focuses on positively charged mineral-based adjuvants, contrary to the claimed invention.

In view of the previously presented Amendment and RCE of January 21, 2010 and the present supplemental response, reconsideration and allowance of the claimed invention is respectfully requested.

#### **No Disclaimers or Disavowals**

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

#### **CONCLUSION**

Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

**Application No.:** 10/509,498  
**Filing Date:** October 27, 2004

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: Feb. 5, 2010

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